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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------------|------------------------|
| 10/508,815 | 09/22/2004 | Yoshinobu Akimoto | 18252 | 5930 |
| 23389 7590 09/24/2007 SCULLY SCOTT MURPHY & PRESSER, PC 400 GARDEN CITY PLAZA SUITE 300 GARDEN CITY, NY 11530 | | | EXAMINER YU, MELANIE J | |
| | | | ART UNIT 1641 | PAPER NUMBER |
| | | | MAIL DATE 09/24/2007 | DELIVERY MODE PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/508,815

Applicant(s)

AKIMOTO ET AL.

Examiner

Melanie Yu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) 1-9 and 12-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10,11 and 29-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/22</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group II, claims 10, 11 and 29-41, in the reply filed on 29 June 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 1-9 and 12-28 have been withdrawn as being drawn to a non-elected invention.

Claim Objections

2. Claims 10, 11 and 29-41 are objected to because of the following informalities: claims 10, 11 and 29-41 depend from claims that have been withdrawn. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 10, 11 and 29-41 are rejected under 35 U.S.C. 102(b) as being anticipated by Gordon et al. (US 5,677,197).

With respect to claims 10, 11 and 35-41, Gordon et al. teach a test piece having a fixed specific binding substance fixed at a predetermined position (assay spots, col. 3, lines 52-63), wherein the specific binding substance binds DNA (col. 3, lines 52-63 and col. 5, lines 10-13).

The method step from which claims 29 and 34 depend, do not provide any structural limitations to the test piece. Furthermore, the claim is a product by process, so the prior art must teach the final product as produced by the method of making recited in the instant

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claims. Gordon et al. teach the required structural limitations that are produced by the method of making in the claims. Therefore the test piece of Gordon et al. reads on the instant claims.

Regarding claims 30, 32 and 33, Gordon et al. also teach a detection substance that differs from or is identical to a label and is fixed on the substrate independently of the specific binding substance (carrier dye is immobilized directly to the substrate, col. 4, lines 49-52 and DNA is immobilized to the substrate, col. 4, lines 31-39, since the substances are bound to the substrate separately, they are fixed at different positions, col. 4, lines 43-48), wherein the detection substance is a dye (col. 4, lines 49-52) and the spectroscopic property of the detection substance, is different from the spectroscopic property of the other substances (col. 4, lines 52-55).

With respect to claim 31, the instant specification, at page 8, lines 23-29, states that a dye is a detection substance that has a spectroscopic property of absorbance. Gordon et al. teach a detection substance of a dye (col. 4, lines 49-52) that has different signals than other substances fixed to the test device. Since both Gordon et al. and the instant specification teach a dye as a detection substance, the dye of Gordon et al. has a spectroscopic property of absorbance.

Although Gordon et al. may not teach the specific methods of making as recited in the instant claims. The rejected claims are drawn to a product by process. The prior art does not need to teach the specific method of making, but must teach the structural limitations produced by the method of making. Gordon et al. teach the structural limitations and the final product produced by the recited method of making and therefore the test device of Gordon et al. reads in the rejected claims as described above.

Conclusion

No claims are allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Yu whose telephone number is (571) 272-2933. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Melanie Yu
Patent Examiner
Art Unit 1641



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09/13/07